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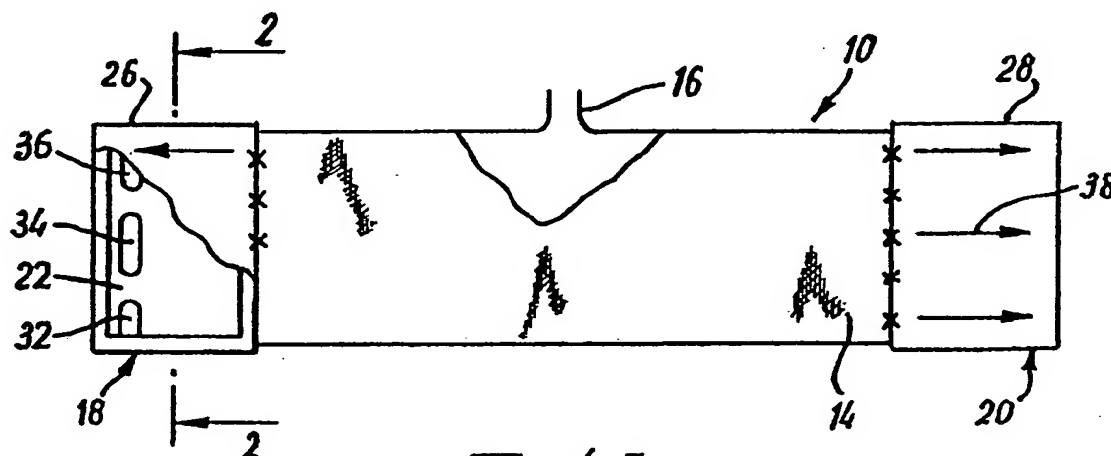
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(54) Vascular graft apparatus

(57) The apparatus comprises a flexible tubular body (14) for forming a prosthetic blood vessel wall and inflatable means such as a balloon catheter or cannula for selectively controlling blood flow through the tubular body during graft insertion and serving to locate and fix the graft in position so as to form communication between two relatively sound portions of the blood vessel. The tubular body may have an aperture for insertion and withdrawal of catheter and may have at each end a connector (18, 19) comprised of a flexible annular sleeve (26, 28) containing a ring (22) formed of a discontinuous band provided with overlapping ends having inter-engaging ratchet means for progressive expansion into sealing engagement with the blood vessel. To facilitate laparoscopic use of the device as an aorta by-pass graft, the apparatus may further include an insertion device (Fig. 6 - not shown) and a retractor (Fig. 5 - not shown)

**FIG. 1****BEST AVAILABLE COPY**

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

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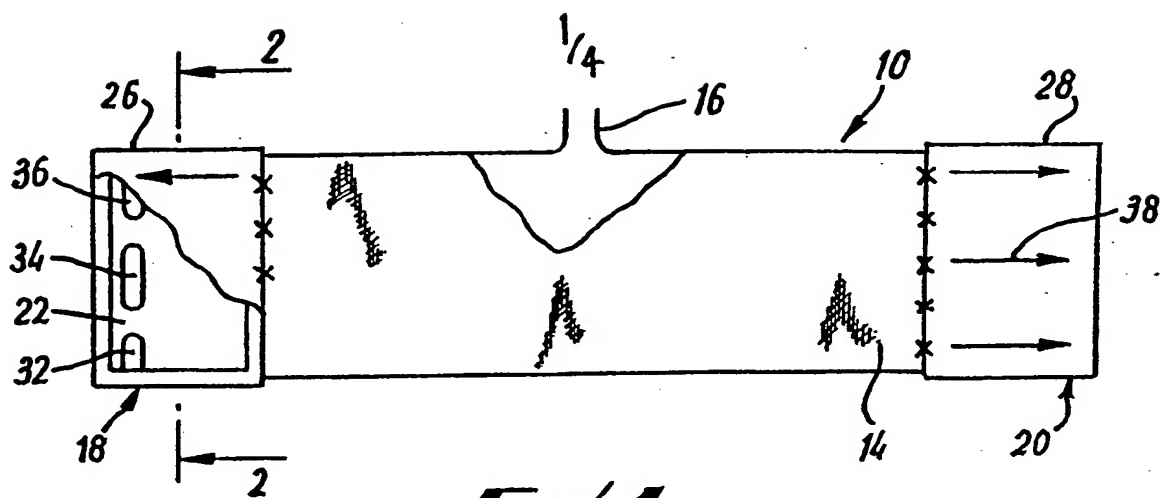


FIG. 1

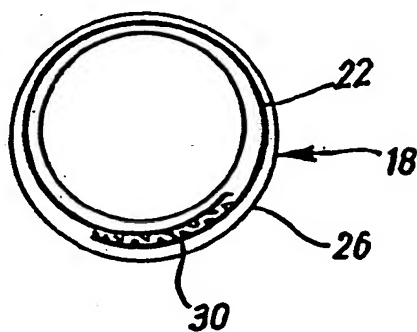


FIG. 2

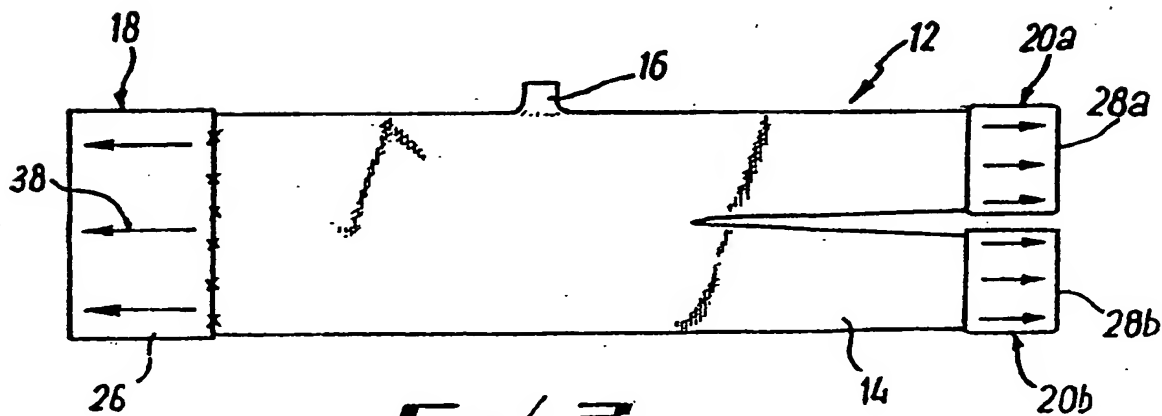


FIG. 3

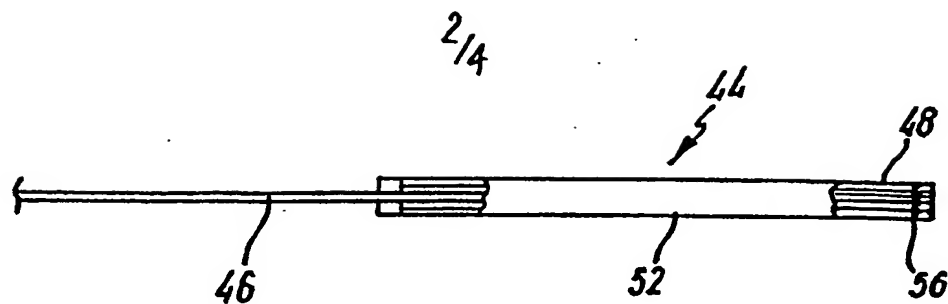


FIG. 4

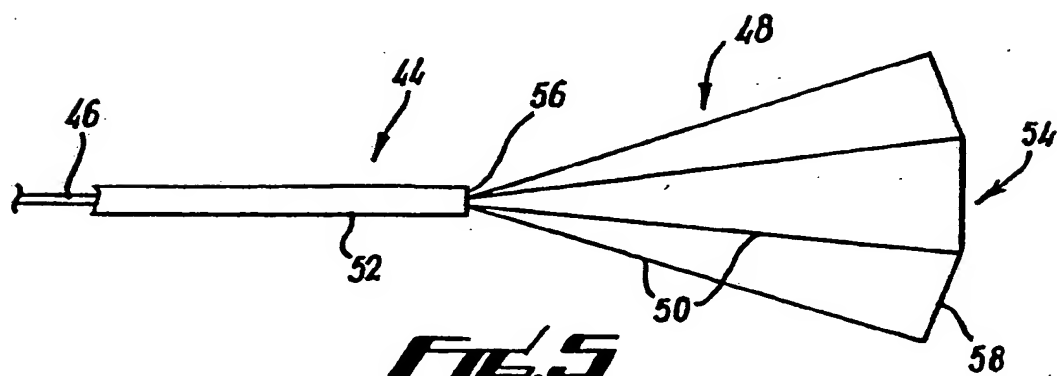


FIG. 5

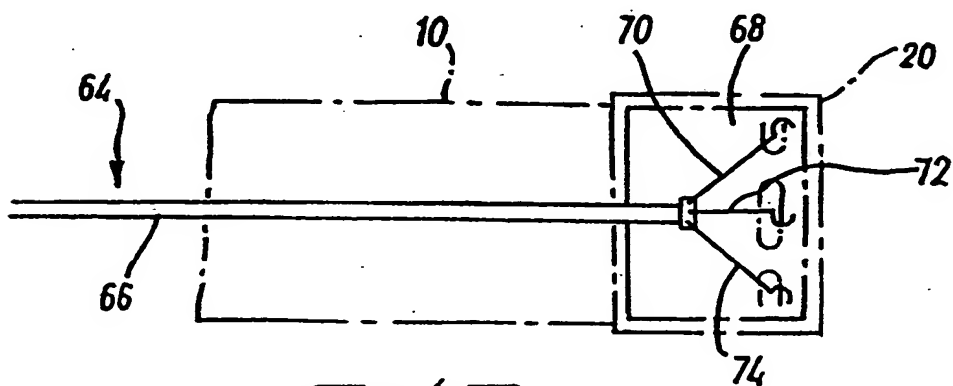


FIG. 6

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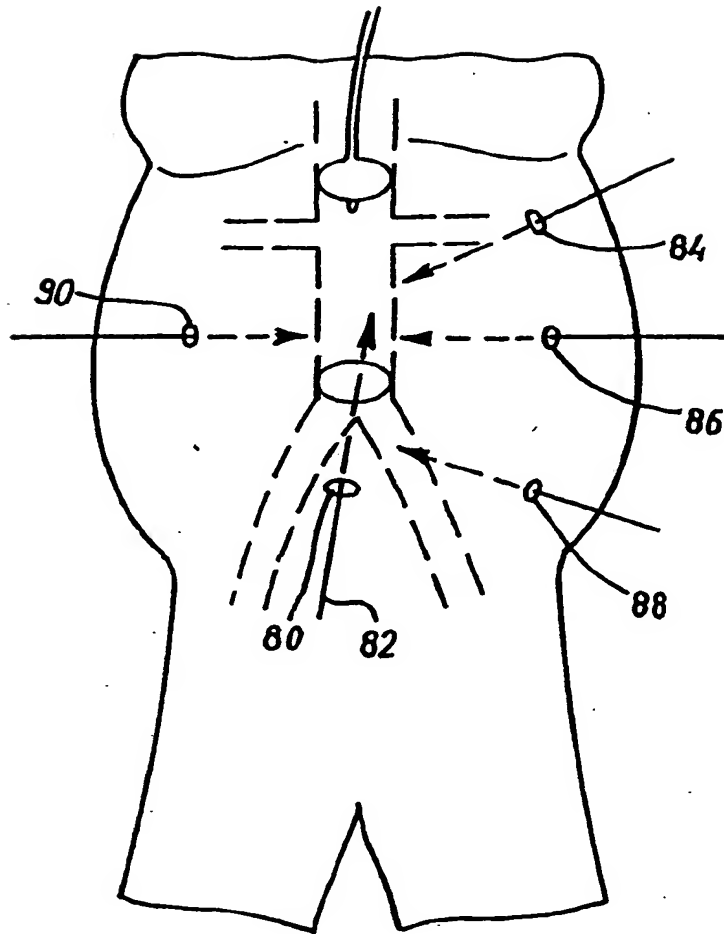
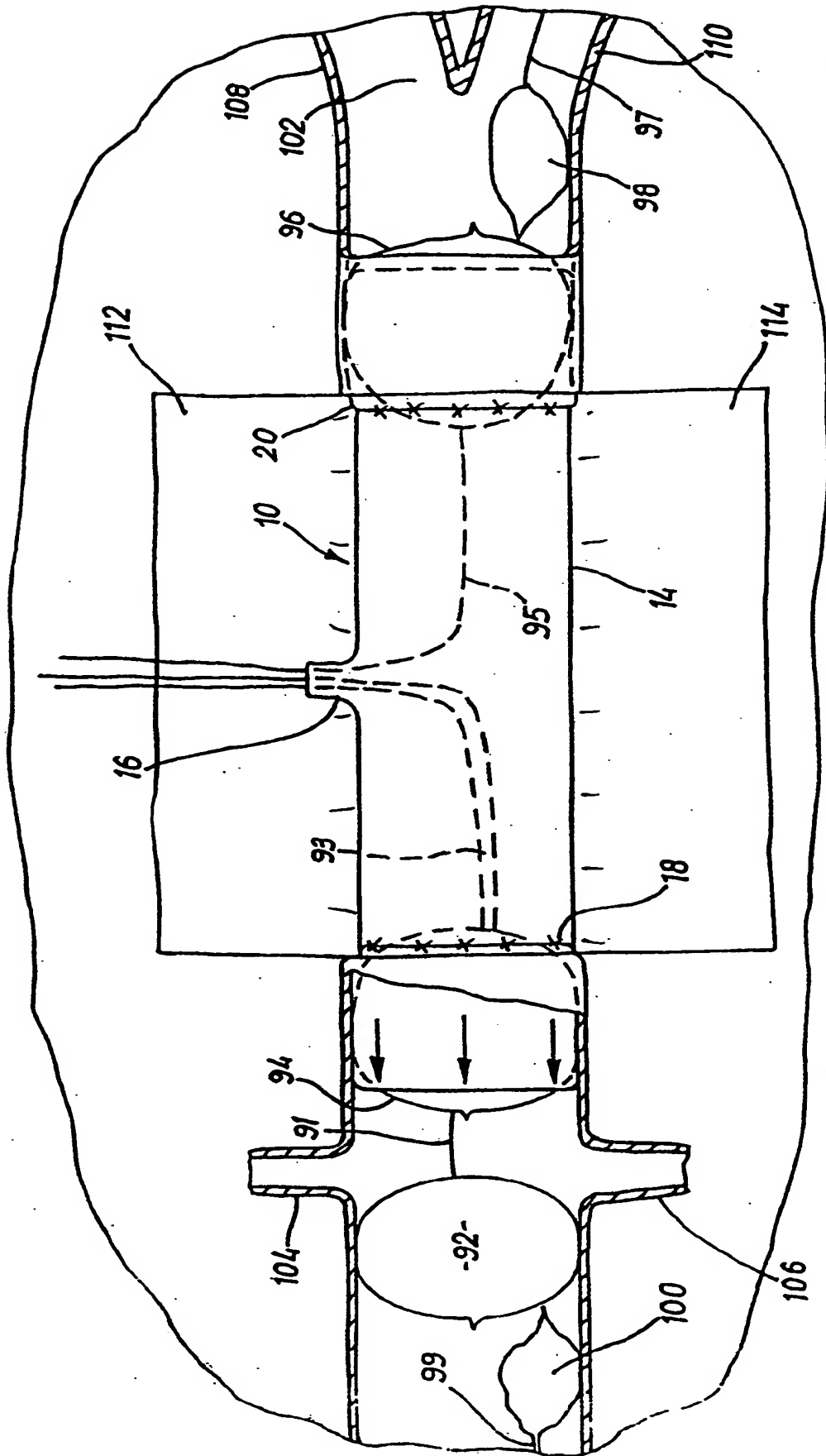


FIG. 1



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FIG. 8

VASCULAR GRAFT APPARATUS

This invention relates to vascular graft apparatus and in particular, but not exclusively, to an aortic graft for insertion during open or laparoscopic surgery . The invention further relates to apparatus and devices for use in the insertion of such a graft.

At present, aortic grafts are inserted during open surgery. Under general anaesthetic, the abdominal wall is incised longitudinally or transversely, cutting the rectus abdominis muscles. The small bowels are then swept to the right side of the abdominal cavity and the peritoneum incised just to the left of the duodenum, dividing the ligament of Treitz. This permits the bowels to be moved to the right side within the abdominal cavity. The small bowel is then pushed under the right lobe of the liver using a self-retaining retractor, or alternatively, are exteriorised in a polythene bag on the right side of the abdominal wall.

Before clamping the aorta below the renal arteries the inferior vena cava is separated from the aorta by blunt dissection and dissection is also carried out on the left side of the aorta. These steps are often difficult due to inflammation associated with aneurysmal disease. In such circumstances, passing a retaining sling around the aorta may cause bleeding from damaged lumbar veins and therefore a straight vascular clamp may have to be used. The common iliac arteries are also dissected and slings

passed around each one, and it is not uncommon for the iliac veins to be injured during such procedures. Both common iliac arteries and the abdominal aorta below the renal arteries are then clamped.

The aorta is then opened longitudinally a few centimetres below the renal arteries to just above the bifurcation of the aorta. Alternatively, the incision may extend to the common iliac arteries. Bleeding from lumbar arteries is controlled by underrunning each artery with a stitch.

The proximal end of a chosen prosthetic graft is stitched to the cut edge of the aorta below the renal arteries. The distal end of the graft is then stitched to the cut edge of the aortic wall just above the bifurcation.

In surgery for obstructive aortic disease, some surgeons may prefer to anastomose the graft to the aorta end-to-side below the renal arteries and end-to-side to the common iliac arteries. If the common iliac arteries and external iliac arteries are diseased then the two limbs of a bifurcated graft are tunneled posterior to the peritoneum to the gravis incision where the graft is anastomosed, end-to-side, to the femoral arteries.

Rather than stitching the graft to the cut portions of the aorta, various proposals have been made for non-sutured arterial anastomosis, including the ringed graft for aneurysm as disclosed by Cave-Bingley and Harris in the British Journal of Surgery Vol. 72 No. 10, October 1985, in which grooved or concave rings are fitted to the

ends of graft and located within the cut edges of the artery, and tape secured around the outside of the artery to hold the ring and graft in place. Before insertion the internal diameter of the neck of the aneurism is measured with calipers and a graft of appropriate size selected. Despite this, it is indicated that serious problems arose when the anastomotic ring was too large to fit comfortably within the aortic lumen and this led the authors to conclude that the diameter of the neck of the aneurism was likely to be a major factor in limiting the usefulness of this technique. A somewhat similar technique has been more recently proposed by Moodie et al in the European Journal of Vascular Surgery No.4, pages 355 - 359 (1990).

The use of a sutureless graft provided with an elastic ring that can attach itself to the vessel wall is described in a preliminary report by Matsumae et al in the Journal of Vascular Surgery, Volume 8, No. 1, July 1988. The graft disclosed is provided with elastic rings made of flat stainless spring steel which are placed at both ends of knitted Dacron grafts and covered with the cuffs of the graft. The ring is compressed and the overlapping ends pinched with forceps. The compressed ring is then introduced into the aorta far enough so that the ring is fully covered with aortic wall and the forceps released. The ring thus expands to its original size and attaches itself to the vessel wall.

Many other variations and approaches may be used though it is generally agreed that any conventional

operation for insertion of an aortic graft is a major procedure with relatively high morbidity and mortality rates. Further, the extensive physical and physiological trauma to the patient caused by the size of the incision, the exposure of abdominal content to cold and relatively dry surroundings, the manipulation of the bowels and prolonged aortic clamping result in an extended recovery period for the patient, who will typically require hospitalization for at least seven days after the procedure.

When compared with open surgery, recent laparoscopic operations on thoracic and abdominal organs allow far quicker patient recovery, for example, patient stay in hospital after a traditional open surgery cholecystectomy operation is four to seven days, while the average stay after a laparoscopic cholecystectomy is only 1.8 days. Thus, it is clear that laparoscopic operations tend to be substantially less traumatic for patients and the shortened period of hospitalization leads to a substantial reduction in treatment costs.

At present there is no existing technique or devices available to surgeons to perform laparoscopic graft insertion to the thoracic or abdominal aorta. There have been various proposals for grafts which may be introduced during laparoscopic procedures, such as the percutaneous endovascular graft experimentally evaluated by Laurence et al, as published in Radiology 1987; 163:357-360. The graft studied consisted of multiple stents in tandem

connected to each other by metallic struts with a Dacron tubing wrapped around the outside of the middle group of stents. The lead and trail stents acted as anchors for the graft, while the internal stents serve to open the Dacron tubing when the device was released from a catheter. However, there has been no notable adoption of such grafts, and the vast majority of aortic grafts continue to be fitted through open surgery.

It is an object of the present invention to provide an improved vascular graft which may be inserted during open surgery, or laparoscopic surgery.

According to the present invention there is provided vascular graft apparatus comprising a flexible tubular body for forming a prosthetic blood vessel wall; and inflatable means for selectively controlling blood flow through the tubular body during insertion of the graft and further serving to locate fixedly the graft in position within the blood vessel.

The inflation means may be in the form of balloon catheters or cannulas for location in the body of the graft. An aperture may be provided in the body to allow insertion and withdrawal of such catheters. Further balloon catheters may also be provided for use in obturating a blood vessel upstream and downstream of the graft while the graft is being located in the blood vessel.

Preferably, the body is provided with two end connectors, one at each end of the body and for locating the body between two spaced portions in a blood vessel,

each connection comprising a flexible annular sleeve fixed to the respective end of the body and containing a ring for progressive expansion in a respective portion of blood vessel into sealing engagement therewith, each ring including locking means to prevent subsequent contraction of the ring.

In use, the graft may be inserted in a diseased or damaged blood vessel using conventional or laparoscopic surgery. The graft is particularly suited for use as an aorta by-pass graft. The connectors, and body, are sized to suit each particular application, and the rings in the connectors are expanded by the inflatable means to provide secure location of the graft in the blood vessel through contact with the inner wall of the respective portion of blood vessel, without causing aneurysm. In the non-expanded configuration, the end connectors are preferably of diameter small enough to be inserted into a body cavity through a catheter.

The rings may be formed of a suitable flexible material such as stainless steel or plastic sheet located within flexible sheaths, which are typically stitched to the body of the graft. The rings are preferably in the form of a discontinuous band with overlapping ends, the opposing faces of the overlapping ends being provided with inter-engaging ratchet means for preventing contraction of an expanded ring. The end portions of the rings may include apertures, ports or other means to allow stitches to be passed through the blood vessel edges and the end

connectors to further secure the graft to the blood vessel.

The apparatus of the present invention may further include an insertion device for use in locating an end of the graft in a blood vessel, the device comprising an elongate body, and a head comprising a plurality of outwardly extending fingers for releasably engaging the stitch-receiving means of the ring of an end connector, with the elongate body extending from the graft for manipulation by a surgeon, the fingers being collapsible to facilitate insertion and removal of the device through a catheter. Use of the device is particularly advantageous in laparoscopic techniques.

Additionally, the apparatus of the present invention may further include a retractor for use in laparoscopic surgery, the retractor comprising an elongate body, a head having a plurality of outwardly extending fingers and a sleeve into which the fingers may be drawn and contained.

The end of the retractor may be inserted into the body of a patient through a catheter with the fingers contained within the sleeve, and the sleeve then retracted to allow the fingers to spread apart to form a hand. The retractor, thus configured, may be utilised to move or retract organs within body cavities. The retractor is particularly suited for use in retracting the small bowel during laparoscopic insertion of an aorta by-pass graft.

These and other aspects of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a part cut-away view of a vascular graft forming part of apparatus in accordance with an embodiment of the present invention;

Figure 2 is a sectional view on line 2-2 of Figure 1;

Figure 3 is a view of a vascular graft for part of apparatus in accordance with a further embodiment of the present invention;

Figures 4 and 5 are views of a retractor forming part of apparatus in accordance with an embodiment of the present invention, for use during laparoscopic insertion of the grafts of Figures 1 or 3;

Figure 6 is view of an insertion device for part of apparatus in accordance with an embodiment of the present invention, for use in inserting the grafts of Figures 1 or 3 in a blood vessel;

Figure 7 is a schematic representation of the torso of a patient in the early stages of a laparoscopic procedure; and

Figure 8 of the drawings is a view of the graft of Figure 1 being inserted in the aorta of the patient of Figure 7.

Reference is first made to Figures 1, 2 and 3 of the drawings, Figures 1 and 2 showing a vascular tube graft 10 and Figure 3 showing a bifurcated graft 12. Both grafts 10, 12 include a flexible tubular body 14 of a suitable fabric material, such as a woven or knitted material as sold under the Dacron trademark. The diameter of the body 14 is typically between 10 and 20 mm and the length of the

graft is decided by the operating surgeon according to measurements obtained during the early stages of surgery.

On a central portion of the body 14 there is an aperture located on a side branch 16 for permitting access to the interior of the body, for purposes which will be described. The branch 16 is typically 2 to 5 mm diameter and of length around 5 mm.

An end connector 18, 20 is provided at each end of the body 14, each connector comprising a ratchet ring 22 (only one shown) located within a respective flexible sheath 26, 28. The proximal sheath 26 (that is, for location closest to the head of the patient) is supplied stitched to the proximal end of the body 14, while the distal sheath 28 is stitched in place by the surgeon after the length of graft required is determined. The sheaths 26, 28 may be formed of Dacron while the ratchet rings 22 are of a flexible material, such as stainless steel. The proximal ratchet ring 22 is shown in Figure 2 and it will be noted that the ring 22 is in the form of a discontinuous band provided with overlapping ends. The ring 22 is typically 5 to 20 mm wide and 10 to 20 mm in diameter. The opposing walls of the overlapping portions of the ring overlap by around 5 mm and the opposing surfaces are provided with keying protrusions 30 which provide a ratchet effect to allow expansion of the ring 22 but to prevent a reduction in diameter of the ring.

Each of the ratchet rings 22 is provided with stitching ports 32, 34, 36 for use in hitching or fixing

the graft to the vascular wall to prevent possible displacement of the graft, as will be described. The stitching ports are located in the anterior and side portions (as seen by the surgeon after insertion) of the ratchet rings 22 to be easily accessible to the surgeon, and the site of each port is indicated by an appropriate marking arrow 38 on the exterior of the respective sheath 26, 28. The middle or front stitching port 34 is 4 mm long and 2 mm wide while the lateral stitching ports 32, 36 are 2 mm in diameter.

In addition to various conventional balloon catheters and other conventional surgical equipment, it is preferred that the grafts 10, 12 are inserted in conjunction with novel devices as illustrated in Figures 4, 5 and 6 of the drawings. Figures 4 and 5 illustrate the end portion of a retractor 44 which may be used in retracting abdominal organs, typically the small bowel. The retractor 44 is intended to be inserted into the body through a suitable cannula and thus must have a small diameter configuration (Figure 4). The retractor 44 comprises an elongate body 46, a head 48 comprising a plurality of fingers 50, and a sleeve 52 in which the fingers 50 are located during insertion and removal of the retractor. The fingers 50 have a memory such that, when the sleeve 52 is retracted over the end of the body 46, the fingers 50 extend outwardly to create a hand 54. The location of the fingers 50 may also be determined by means of an apertured end plate 56 provided in the sleeve 52, the apertures in

the plate 56 being oriented to facilitate the positioning of the fingers 50 to provide the desired shape of hand. The ends of the fingers 50 are joined by a length of filament 58 to assist in locating the ends of the fingers 50 relative to one another. Alternatively, the end of the retractor 44 may be located within a flexible bag or pouch such that on extending the fingers 50 a webbed hand is created.

Figure 6 of the drawings illustrates an insertion device 64 for use in locating the ends of the grafts 10, 12 in the cut blood vessel. The device 64 comprises an elongate body 66 and a head 68 comprising three outwardly extending fingers 70, 72, 74 for releasably engaging the stitching ports of the rings in the end connectors 18, 20. At least the outer fingers 70, 74 are pivotally mounted to the body 66 to permit the head 68 to be collapsed to facilitate insertion and withdrawal of the device 64 through a catheter.

The use of the grafts 10, 12, retractor 44 and insertion device 64 will now be described, also with reference to Figures 7 and 8 of the drawings, with reference to the description of an operative procedure for inserting a graft. As the insertion of the grafts 10, 12 differs slightly, the insertion of the tubular graft 10 will be described first.

Initially, the abdominal cavity of the patient is insufflated with CO₂ to a pressure of 12 to 14 mm Hg. A first incision 80 is made below the umbilicus and a 20 mm

diameter cannula 82 introduced through the incision 80. The cannula 82 is then down-sized to 10 mm and a laparoscope introduced through the cannula to permit visualisation and inspection of the peritoneal cavity, and the other sites of cannula insertion may then be sited under vision, therefore avoiding injury to intra-abdominal organs. Three 10 mm incisions 84, 86, 88 are made on the left side of the abdominal wall of the patient, lateral to the midclavicular line. The most superior and inferior incisions 84, 88 are each provided with 10 mm cannula for introduction of dissectors, graspers and suction. The intermediate incision 86 is used for the laparoscopic cannula, which is moved from the first incision 80. A fifth incision 90 is made on the right side of the abdominal wall and lateral to the midclavicular line. This 5 to 10 mm incision is used for introduction of graspers, retractors or dissectors.

The operating table on which the patient is supported is initially tilted at 25 to 30 degrees to the right as viewed by the patient, thus allowing the small bowel to move to the right side of the abdominal cavity. This operation may be facilitated using the retractor 44 described above. Head down tilt of the operating table, together with hitching the greater omentum and transverse colon with a band to the interior abdominal wall at the xiphisternum, provides clear access to the appropriate area of the abdominal cavity. The peritoneum on the left side of the aorta is longitudinally cephalad and caudad

incised, dividing the ligament of Treitz. The inferior mesenteric artery may have to be clipped and divided if a longitudinal incision is to be made in the aorta.

The diameter and length of the required graft is determined by direct measurement using the laparoscope. The diameter of the ratchet rings 22 of the selected graft should be slightly larger than the internal diameter of the healthy portion of the aorta to which the graft is to be secured. As mentioned above, the proximal end connector 18 is preferably fixed to the graft body 14 by the manufacturer and the distal connector 20 is stitched to the body of the graft once the measurements have been taken, allowing the surgeon to tailor the graft to the patient.

Before the graft is inserted, a number of balloon cannulas are inserted into the graft through the side branch 16. In the case of the tube graft 10, three cannulas 91, 93, 95 provided with balloons 92, 94, 96 are utilised, as illustrated in Figure 8. The balloons are utilised to occlude the aorta and to expand the ratchet rings to their required operational sizes. The graft 10, together with the cannulas 91, 93, 95 is then inserted through the 20 mm infra-umbilical cannula 82 into the peritoneal cavity.

A catheter 97, also provided with a balloon 98 is introduced percutaneously through a femoral artery and a further catheter 99, also provided with a balloon 100, is introduced through the left subclavian artery. The

femoral balloon 98 is located above the bifurcation 102 of the aorta and the left subclavian balloon 100 is located in the aorta about 5 cm above the renal arteries 104, 106. Both balloons 98, 100 are inflated to completely occlude the aorta.

A small incision is then made in the anterior wall of the aorta about 5 cm below the renal arteries 104, 106 and the two proximal balloon cannulas 91, 93 are extended from the proximal end of the graft through the incision to locate a first balloon 92 above the renal arteries 104, 106 and the second balloon 94 below the renal arteries. The infrarenal second balloon 94 is inflated to occlude the aorta, and the left subclavian balloon 100 is then deflated to resume blood supply to the kidneys. This procedure will take in the region of five minutes. Throughout the remainder of the operation the left subclavian balloon 100 may be inflated in case of difficulties to stop blood loss from the open aorta.

The aorta is now opened longitudinally, from 3 cm below the renal arteries 104, 106 to 3 cm above the bifurcation 102 to form flaps 112, 114, which are turned outwards into the position shown in Figure 8. The lumbar arteries (not shown) are underrun with stitches to stop bleeding therefrom.

The collapsed proximal end connector 18 of the graft 10 is then introduced through the aortic stump, using the insertion device 64 (not shown in Figure 8). The suprarenal first graft balloon 92 is then inflated to occlude the aorta and the infrarenal graft balloon 94 is

deflated to allow the proximal end connector 18 to advance into position below the suprarenal inflated balloon 92 and the renal arteries 104, 106. The infrarenal graft balloon 94 is now located inside the ratchet ring 22 of the connector 18 and is inflated to open the ring to the required calibre to impact the end connector wall firmly against the aortic wall. The ratchet ring 22 is opened by 1 to 2 mm more than the calibre of the graft. The suprarenal graft balloon 92 is then gradually deflated to allow renal blood flow. Again, this stage of the procedure should not take more than five minutes.

The collapsed distal end connector 20 is then introduced through the distal aortic stump after deflation of the femoral balloon 98 which was occluding the aorta just above its bifurcation 102. The occluding function of this balloon 98 is taken over by the graft distal balloon 96, which is inserted at the same time as the introduction of the proximal graft balloon cannula 91.

The ratchet ring is located in the desired position and expanded by inflating the distal graft balloon 96 inside the ring to open the ring up to 0.5 to 1 mm more than the graft body and aorta diameter until the ratchet ring is firmly attached to the aortic wall.

The distal balloon 96 is then deflated slowly and the distal end of the graft is observed to determine whether any bleeding occurs. The distal graft balloon 96 is then re-inflated and the proximal infrarenal balloon 94 gradually deflated to see if there is any bleeding at the

proximal end of the graft. If any bleeding is observed, the appropriate ratchet ring should be open more widely by inflation of the respective balloon. If there is no bleeding the distal graft balloon 96 is gradually deflated to re-establish blood circulation to the lower limbs.

The graft balloons 92, 94, 96 are now withdrawn to the centre of the graft body 14, still leaving the auxiliary balloon 100 in place.

Non-absorbable stitches are then passed through the stitching ports 32, 34, 36 in the ratchet rings 22 to stitch the graft to healthy aortic wall which will not be subject to pressure by the ratchet rings 22; this is a precautionary step to prevent displacement of the graft in the event that pressure atrophy of the aortic wall occurs.

Following stitching, all of the graft balloon cannulas 91, 93, 95 are removed and the graft side branch 16 is closed, by clamping and stitching. The flaps of aortic tissue 112, 114 are then re-positioned over the graft 10 and the peritoneum re-positioned to isolate the graft from the small bowel. The peritoneal cavities are then inspected with the laparoscope. If everything is in order the greater omentum and transverse colon are released and all instruments removed under vision. Finally, the laparoscope is removed and the peritoneal cavity deflated. The wounds are then closed.

For the bifurcated graft 12, the procedure is largely similar, though four balloons cannulas are inserted with the graft 12, the extra balloon being necessary as the

common iliac arteries must be individually occluded, and the two end connectors 20a, 20b expanded. Accordingly, two femoral catheters must be utilised. Also, the incision made by the surgeon in the aorta extends to the common iliac arteries 108, 110, into which the end connectors 20a, 20b are introduced after the insertion of the respective femoral balloon.

Thus, the present invention allow the insertion of an aortic graft, using laparoscopic techniques. The graft may of course be utilised in other regions on the body, and in open surgery if desired. It should also be understood that the particular embodiment described herein is merely exemplary, and various modifications and improvements may be made to the apparatus described without departing from the scope of the present invention.

CLAIMS

1 A vascular graft apparatus comprising a flexible tubular body for forming a prosthetic blood vessel wall, and inflatable means for selectively controlling blood flow through the tubular body during insertion of the graft and further serving to locate fixedly the graft in position within the blood vessel, therefore forming communication between two relatively sound portions of the said blood vessels.

2 A vascular graft apparatus comprising a flexible tubular body as claimed in claim 1. The said tubular body is provided with two end connectors, one at each end.

3 A vascular graft apparatus comprising a flexible tubular body as claimed in claim 1. The said tubular body is provided with two end connectors, one at each end as claimed in claims 1 and 2, the said connectors comprising a flexible annular sleeve fixed to the respective end of the flexible tubular body. The said annular sleeve contains a ring for progressive expansion in a respective portion of blood vessel achieving sealing engagement therewith.

4 A vascular graft apparatus comprising a flexible tubular body which is provided with two end connectors. The said end connectors containing a ring each as claimed in claims 1, 2 and

3. Each said ring including a locking means to prevent subsequent contraction of the expanded ring.

5 Each end connector and its ring in the non-expanded configuration are preferably of a diameter small enough to be inserted into a body cavity through a small caliber cannula

6 Each ring as claimed in claim 4 may be formed of a suitable flexible material such as stainless steel or plastic sheet located within the flexible annular sheaths which are typically stitched to the end portions of the body of the graft.

7 The rings, as claimed in claim 6, the said rings are preferably in the form of a discontinuous band with overlapping ends.

8 The rings are preferably in the form of a discontinuous band with overlapping ends as claimed in claim 7. The opposing faces of the said overlapping ends being provided with inter-engaging ratchet means for preventing contraction of an expanded ring.

9 A vascular graft apparatus comprising a flexible tubular body. The said tubular body may be provided with end connectors, one at each end of the said tubular body. Each end connector containing a ring as claimed in claims 1,2,3,4,5,6,7 and 8, the said rings in the connectors are expanded by the inflatable means to provide secure location of the graft with the inner wall of

the respective portion of blood vessel.

10 The end portion of the rings may include apertures, ports or other means to allow stitches to be passed through the blood vessel edges and the end connectors to further secure the said vascular graft to the blood vessel.

11 A vascular graft apparatus comprising a flexible tubular body as claimed in claim 1. The said tubular body may be provided with an aperture in the said body to allow insertion and withdrawal of the inflatable means.

12 A vascular graft apparatus as claimed in claim 1, may further include a retractor to facilitate insertion of the said vascular graft laparoscopically. The said retractor comprising an elongated body, a head having a plurality of outwardly extending fingers and a sleeve into which the fingers may be drawn and contained.

13 The retractor, as claimed in claim 12, has a sleeve. Retraction of the said sleeve allows the fingers to spread apart to form a hand.

14 The retractor, as claimed in claim 12 and 13 has an apertured end plate. The location of the fingers of the said retractor may be determined by means of the said apertured end plate provided in the sleeve of the said retractor.

15 The retractor, as claimed in claims 12,13 and 14, the said retractor's fingers may be joined by a length of filament.

16 The end of the said retractor may be located within a flexible bag or a pouch such that on extending the fingers a webbed hand is created.

17 The vascular graft apparatus as claimed in claim 1, insertion laparoscopically into the vascular lumen requires an insertion device for use in locating the end of the graft in the blood vessel.

18 The insertion device as claimed in claim 17. The said device comprising an elongated body and a head comprising a plurality of outwardly extending fingers for releasably engaging the said ring of an end connector.

19 The insertion device, as claimed in claims 17 and 18, wherein the fingers being collapsible to facilitate insertion and removal of the said vascular graft apparatus through a catheter.

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